In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-794V

(to be published)

MARY SAVILLE ,	Chief Special Master Corcoran
Petitioner,	
v.	Dated: August 28, 2023
SECRETARY OF HEALTH AND HUMAN SERVICES,	
Respondent.	

Renee J. Gentry, Vaccine Injury Clinic, George Washington University Law School, Washington, DC, for Petitioner.

Madelyn Weeks, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On January 25, 2021, Mary Saville filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] Petitioner alleges she suffered cellulitis following receipt of the quadrivalent influenza ("flu") and pneumococcal vaccines on November 5, 2018. Petition (ECF No. 1) at 3.

The parties have agreed that the matter could reasonably be resolved via ruling on the record, and filed briefs in support of their respective positions. *See* Petitioner's Motion, dated March 29, 2023 (ECF No. 37) ("Mot."); Respondent's Opposition, dated April 28, 2023 (ECF No. 38) ("Opp."). Now, after review of the medical records and briefs, I **GRANT** entitlement.

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

I. Factual Background

On November 5, 2018, Petitioner received flu[3] and pneumococcal[4] vaccines in her left deltoid from Tanuja Sharma, M.D., at Tampa General Medical Group. Ex. 1 at 281, 302–03; Ex. 9 at 1 ("Saville Aff. I"); Ex. 16 at 1 ("Saville Aff. II"). Petitioner's pre-vaccination medical history was significant for depression, anxiety, hypothyroidism, transient ischemic attack ("TIA"), arteriovenous malformation, and asthma. Ex. 1 at 5, 144; Ex. 18 at 8.

According to Petitioner's affidavit, within hours of being vaccinated, she experienced pain and stiffness at the injection site and "flu-like" symptoms, including chills, aches, weakness, and a fever, for which she took Tylenol and ibuprofen. Saville Aff. I at 2; Saville Aff. II at 1–2. The next morning (November 6, 2018), she reported that her flu-like symptoms had persisted despite her taking over-the-counter pain medication. Saville Aff. I at 2; Saville Aff. II at 2. The pain and soreness made it difficult to move her arm. Saville Aff. I at 2; Saville Aff. II at 2.

On November 7, 2018, Petitioner presented to nurse practitioner ("NP") Mallory Lott at Tampa General Medical Group Westchase, reporting that she had developed headache, nausea, arm pain and swelling, and fever the day of her immunizations. Ex. 1 at 327. An examination showed erythema, edema, and warmth over the left upper arm, which was firm and tender to touch. *Id*. at 329–30. Her lab work noted a white blood cell count of 27.1, absolute neutrophil count of 24,905, and monocyte absolute value of 1,301. *Id.* at 326. Petitioner received a differential diagnosis of cellulitis versus inflammatory reaction. *Id*. at 331. She was treated with cephalexin and advised to apply heat to the arm as needed along with regular use of ibuprofen. *Id*. NP Lott opined that because Petitioner had received yearly flu shots without experiencing adverse reactions, the reaction was probably due to the pneumococcal vaccine.[5] *Id*.

The next day (November 8, 2018), Petitioner presented to the emergency room ("ER") at the Medical Center of Trinity. Ex. 2 at 21; Saville Aff. I at 3; Saville Aff. II at 2. She reported that she had recently received flu and pneumovax vaccinations, and "[s]everal hours later [developed]

[3] Five years prior, Petitioner received the influenza trivalent preserve vaccine, but she had never received the quadrivalent influenza vaccine. Saville Aff. I at 1.

[4] The pneumococcal PPSV 23 vaccine that Petitioner received is not listed on the Vaccine Injury Table as a "covered" vaccine. 42 C.F.R. § 100.3. As such, Petitioner would be precluded from receiving compensation under the Act if the evidence demonstrated that the PPSV 23 vaccine *alone* caused her injuries, and she could not otherwise base a claim on receipt of this vaccine.

[5] According to Petitioner, NP Lott provided an incorrect summary. Mot. at 4 n.1. Petitioner's medical records indicate that her last receipt of the flu vaccine was in November 2013, five years prior, and she did not receive the quadrivalent flu vaccine at that time. Ms. Saville had in fact never before received the quadrivalent version before, and received the trivalent formulation five years prior. Ex. 1 at 281.

a small red area that has progressed over several days." Ex. 2 at 21. She also complained of shortness of breath. *Id*. A physical exam of the skin established that Petitioner had "a large area of erythema with central induration over the left arm . . . [t]he erythematous area is quite warm compared to the surrounding tissue. It is minimally tender." *Id.* at 23. Petitioner was diagnosed with cellulitis of the left upper arm. *Id*. at 43. She was given cefazolin and vancomycin in the emergency room, and admitted to the hospital for further treatment. *Id*. at 26, 28. A CT scan showed possible cellulitis or fasciitis. *Id*. at 25.

On November 9, 2018, Petitioner was seen by a surgeon, Keith Chisholm, M.D., who concurred with the cellulitis diagnosis, offering the opinion that Petitioner had a methicillin-resistant staphylococcus aureus infection in her left arm. Ex. 2 at 46–47. Dr. Chisholm recommended surgery because of the ongoing erythema, redness, and pain. *Id.* at 47. Notably, Dr. Chisholm believed this "may have been introduced into subcu[sic] after her vaccinations." *Id.* After an infectious disease consult with Todd Groom, M.D., Dr. Chisolm also agreed with the diagnosis of cellulitis/fasciitis that had failed oral antibiotics. *Id.* at 48–51. On November 10, 2018, Petitioner was taken to surgery after a CT scan showed evidence of significant cellulitis with fasciitis and a suspected developing abscess. *Id*. at 48, 50. Dr. Chisholm performed incision and drainage of the left arm. *Id*. at 182–83.

Petitioner was discharged on November 12, 2018, with a diagnosis of left upper extremity cellulitis with developing abscess, status post incision and drainage. Ex. 2 at 17; Saville Aff. I at 3; Saville Aff. II at 3. She was directed to take doxycycline orally for ten days. Ex. 2 at 17–18.

Six months later, on May 17, 2019, Petitioner presented to her primary care provider, Kimberly Lamartin, M.D., at Tampa General Medical Group Armenia ("Armenia"), with complaints of fatigue and bruising easily. Ex. 5 at 3-5, 19;[6] Saville Aff. II at 3. She reported that she had previously experienced an adverse reaction to the flu and pneumonia vaccines. *Id.* at 19. She also reported persistent fatigue since that time but noted that she had four children, including a 13-year-old with a significant medical condition. *Id*.; Saville Aff. II at 3.

Petitioner's physical exam was normal, with no skin rash. Ex. 5 at 21–22. She was diagnosed with fatigue, anxiety, depression, reaction to flu vaccine, and a history of anaphylaxis, chronic low back pain, TIA, mild intermittent asthma, and hypothyroidism. *Id*. at 26. Dr. Lamartin noted that Petitioner's fatigue was "likely primarily due to reduced sleep, multiple demands. . . ." *Id*. at 25. In an addendum written later that day, Dr. Lamartin noted that Petitioner had flu-like symptoms and progressive erythema after receiving influenza and Pneumovax immunizations in

[6] According to Petitioner, there is an error in the medical records in Ex. 5 at 5. Mot at 6 n.3. Dr. Lamartin erroneously indicates "November 2019 with progressive erythema . . .", but the records were created on May 17, 2019. Ex. 5 at 5. Therefore, the date mentioned had not yet occurred, and Petitioner clarified that this record should read "November 2018." Mot at 6 n.3.

November 2018. *Id*. at 43. She further wrote that Petitioner's presentation was similar to other case reports with Pneumovax 23, and that she "[t]ypically would defer further immunization for influenza or pneumovax due to [the] severity of [the] reaction," but because Petitioner had a son with significant immune deficiency, Dr. Lamartin wanted to refer Petitioner to an allergist for their opinion on receiving future vaccinations. *Id*.

Between May 17, 2019, and March 8, 2021, Petitioner was treated for unrelated health issues, including a broken tooth, sinusitis, and asthma. *See* Ex. 5 at 43, 55–60; Ex. 6 at 4–5; Ex. 7 at 8–9. On March 8, 2021, Petitioner presented to Danaysi Del Agua, APRN, at Armenia for a refill of levothyroxine. Ex. 18 at 2. She reported that her hypothyroidism symptoms, including fatigue, had been worsening. *Id*. at 2, 4. Petitioner expressed interest in receiving the COVID-19 vaccine, but stated that she had an allergy to the flu vaccine and Dr. Lamartin had recommended that she see an allergist before proceeding with the vaccine. *Id*. at 2.

Two days later, on March 10, 2021, Petitioner established care with Roberto Garcia, M.D., an allergist. Ex. 17 at 23. She was seeking a recommendation on whether it was safe for her to receive the COVID-19 vaccine. *Id*. Petitioner reported that in November 2018, she received pneumococcal and influenza vaccines and within 48 hours had complications, including infection, abscess, and cellulitis. *Id*. Petitioner stated that she was otherwise in good health, "but she is now affected with chronic fatigue." *Id*. A pulmonary function test was administered and revealed moderate airway obstruction. *Id*. at 24. Dr. Garcia prescribed montelukast and Flonase spray. *Id.* Petitioner attended follow-up appointments with Dr. Garcia through July 2021 to receive allergy shots. *See generally* Ex. 17. Dr. Garcia's records do not reflect any recommendations for or against further vaccinations.

Petitioner returned to Dr. Lamartin on June 2, 2021, for a follow-up visit. Ex. 18 at 8. She was taking levothyroxine, and her fatigue symptoms had improved. *Id*. Petitioner reported receiving both COVID-19 vaccines without any adverse events. *Id*. She also complained of left arm soreness, which she associated with her adverse reaction to the flu and pneumonia vaccines. *Id*.

On December 2, 2021, Petitioner presented to Dr. Lamartin for a physical examination. Ex. 18 at 21. She reported being diagnosed with Ehlers-Danlos Syndrome and planned to establish care with a cardiologist and a geneticist. *Id*. Dr. Lamartin ordered a brain MRI and referred Petitioner to neurology. *Id*. at 25. Petitioner received a flu vaccination in her right deltoid, (despite notes in her medical records that she had an allergy to influenza virus vaccines) to which Dr. Lamartin noted that Petitioner "tolerated [it] well." *Id*. at 27. There was no indication of an adverse reaction to this vaccine.

Petitioner underwent a brain MRI without contrast on December 15, 2021, which showed a prominent developmental venous angioma but no associated hemorrhage, and was otherwise within normal limits. Ex. 18 at 28.

Petitioner returned to Dr. Lamartin on December 17, 2021, for an unrelated health matter. Ex. 18 at 29. During this visit, Petitioner complained of chronic left arm pain since an injection complication. *Id*. at 34. She did not report any adverse reactions to her recent flu vaccination. Petitioner reported that a friend who is a physical therapist advised her she might have a good response to localized therapeutic massage. *Id*. at 30. Dr. Lamartin placed a referral to physical therapy. *Id*. at 34. No further medical records have been filed, though Petitioner states that she still feels pain when applying pressure to the scars that formed at each injection site.[7] Saville Aff. I at 4; Saville Aff. II at 3.

II. Expert Report

Only one expert report was offered in this case—from Dr. Christina DeWitt, a board-certified dermatologist, prepared one written report for Petitioner in support of the contention that vaccines can cause cellulitis, abscess, and possibly fasciitis, and that the flu vaccine did so in this case. Report, dated October 31, 2022, filed as Ex. 20 (ECF No. 33-2) ("DeWitt Rep.").

Dr. DeWitt received her undergraduate and medical degree from the University of Missouri – Columbia, Schoon of Medicine. *Curriculum Vitae,* filed as Ex. 21 on October 31, 2022 (ECF No. 33-3) ("DeWitt CV") at 1; DeWitt at 1. Dr. DeWitt completed an internship in internal medicine and residency in dermatology at Southern Illinois University in Springfield, Illinois, before completing a fellowship in immunodermatology at the National Institutes of Health in Bethesda, Maryland. DeWitt CV at 1; DeWitt Rep. at 1. She is now an Assistant Professor of Clinical Dermatology on faculty with the Georgetown University School of Medicine's Department of Dermatology. DeWitt CV at 1; DeWitt Rep. at 1. Dr. DeWitt is licensed to practice medicine in Maryland and the District of Columbia, and is board certified by the American Board of Dermatology. DeWitt CV at 1–2; DeWitt Rep. at 1. She has also published peer-reviewed articles in the dermatology literature. DeWitt CV at 2; DeWitt Rep. at 1.

Dr. DeWitt spent most of her expert report summarizing the medical records. DeWitt Rep. at 2–7. Of notable references, Dr. DeWitt observed (relying on Petitioner's affidavits) that within hours of receiving two vaccinations, Petitioner began experiencing significant pain, redness and swelling at the local site of the injection. DeWitt at 7; Saville Aff. I at 2; Saville Aff. II at 1–2. Within two days, the localized reaction progressed in both extent and severity, including the development of flu-like systemic symptoms. DeWitt at 7; Saville Aff. I at 2; Saville Aff. II at 2.

[7] Petitioner's daughter and husband have submitted unsworn witness statements discussing the impact of Petitioner's injury on herself and their family. *See generally* Ex. 13–14.

Petitioner had an elevated white blood cell count, and she was diagnosed with cellulitis and started on oral cephalexin. DeWitt at 7; Ex. 1 at 326, 331. During the initial diagnosis of cellulitis, the cause was attributed to the vaccines. DeWitt at 7; Ex. 1 at 331. Her symptoms persisted and progressed, along with new developments—fever, necessitating the addition of oral clindamycin and evaluation in the Emergency Department. DeWitt at 7; Ex. 2 at 21. Having failed oral antibiotics, her white blood count remained elevated, and a CT scan was concerning for cellulitis and possibly fasciitis, which prompted admission to the hospital for intravenous antibiotics. DeWitt at 7; Ex. 2 at 25–26, 28. Despite her labs improving on IV antibiotics, she continued to experience significant redness and pain, and ultimately, she required surgery to provide clinical relief. DeWitt at 7; Ex. 2 at 182–83.

Petitioner was diagnosed with a concurrent cellulitis and abscess occurring at the site of the two vaccine injections. DeWitt at 8. In a large review of medically attended infectious events following parenteral vaccination, localized clinical syndromes were the most common, which include the following diagnoses: cellulitis, infectious abscess, necrotizing fasciitis, pyomyositis, osteomyelitis and septic arthritis. Among these, cellulitis is the most common. DeWitt at 8; I. Cook, *Sepsis, Parenteral Vaccination and Skin Disinfection*, 12 Hum. Vaccines & Immunotherapeutics 2546, 2547–48, 2550 (2016), filed as Ex. 24 (ECF No. 33-6) ("Cook"). Cook did not demonstrate a higher risk association with any specific vaccination, but it provides evidence that vaccines have the potential to cause serious local infections requiring medical intervention. DeWitt at 8; Cook at 2555.

Treater views associating Petitioner's vaccinations with her injuries were also, in Dr. DeWitt's view, supportive of the conclusion that the vaccines played a causal role. DeWitt at 7; Ex. 1 at 331 (NP Lott); Ex. 2 at 47 (Dr. Chisholm). Her treaters otherwise did not propose an alternative cause. DeWitt at 7.

Comparing the effects of the flu *versus* pneumococcal vaccine, Dr. DeWitt opined that both could have been jointly contributory, despite medical record notations addressing only one vaccine. DeWitt at 8. For instance, while a note on November 7, 2018 from NP Lott that Petitioner "had never had a reaction to a flu shot before and received them every year so it was more likely a reaction to the pneumococcal vaccine," Dr. DeWitt observed that it was actually five years since Petitioner received any season flu vaccine, and the one she had last received was a different formulation. DeWitt at 7; Ex. 1 at 331. In any event, since Petitioner's injury was infectious in nature, prior and subsequent immunologic reactions to vaccines were irrelevant. DeWitt at 8. This, Dr. DeWitt argued, was the most likely reason why Dr. Garcia provided no specific recommendations for or against vaccinations, despite this being the primary reason for referral. DeWitt at 8; Ex. 17 at 23–25. Another discussion from Petitioner's PCP on May 17, 2019, evaluated Petitioner's fatigue and referenced a vaccine-associated reaction pertaining to the flu vaccine, but made no mention of the pneumococcal vaccine. DeWitt at 7–8; Ex. 5 at 4. In fact, a

"[r]eaction to influenza immunization" is the sole diagnosis listed on the referral to Allergy and the only vaccination-related diagnosis documented during this encounter. DeWitt at 8; Ex. 5 at 68.

On the other hand, a different contemporaneous treater, Dr. Lamartin, expressed concern about the pneumococcal vaccine as a cause of Petitioner's reaction, because her presentation was "similar to other case reports with pneumovax-23," but no substantiation for this contention could be found in the record. Ex. 5, at 4–5, 15. However, Dr. Dewitt opined, because the vaccinations were administered at the same time and within an inch of each other, it would be medically impossible to assign causation for an infectious local event to one over the other, so both likely played a role. DeWitt at 8. Unlike cutaneous hypersensitivity reactions, the infectious nature of the cellulitis injury provides no morphologic hints or clues as to how the organism entered the skin, so it is impossible to claim the bacteria was preferentially introduced via the needle of one vaccine over the other. DeWitt at 8; *Preventing and Managing Adverse Reactions*, Ctr.'s Disease Control & Prevention 1, 4 (2022), filed as Ex. 22 (ECF No. 33-4) (discussing vaccine reactions generally); J. Kelso, *Allergic Reactions to Vaccines*, UpToDate 1, 3–4 (2022), filed as Ex. 23 (ECF No. 33-5) (same).

Finally, Dr. DeWitt did not address the question of timing for onset of Petitioner's injury, other than noting that Petitioner's affidavits stated that her symptoms began within hours of vaccination.

III. Procedural History

This case was initiated in January 2021, and was eventually reassigned to me after being presided over for a period of time by a different special master. ECF No. 17. The parties then began engaging in settlement discussions but were unable to reach an agreement. ECF No. 30. Respondent filed his Rule 4(c) Report on May 16, 2022. ECF No. 31. Petitioner subsequently filed Dr. DeWitt's report. ECF No. 33. Respondent then filed an amended Rule 4(c) Report on January 18, 2023, stating that he would not continue to defend the case during further proceedings on entitlement, and requested a Ruling on the Record instead. ECF No. 36. I thus set a briefing schedule and the matter is now ripe for resolution.

IV. Parties' Arguments

Petitioner argues that she was correctly diagnosed with concurrent cellulitis and abscess. Mot. at 12–14. Statements from Dr. DeWitt, she purports, support a biologically plausible connection between the flu vaccine and concurrent cellulitis and abscess, mediated by an infectious event at the site of the vaccine needle's incision. Mot. at 14–16. Ms. Saville next claims that she has demonstrated a logical sequence of cause and effect that the vaccines she received "did cause" her injury. *Id*. at 16–18. In support, she notes that her clinical picture was consistent with cellulitis as she experienced swelling, redness, and erythema at the injection site, and treating physicians

allowed for the possibility that the vaccine was related to her injuries. *Id*. Finally, the timing of her onset—occurring hours after administration of the vaccines with symptoms worsening over the next two to three days—is medically-acceptable. *Id.* 18–19.

In opposing entitlement, Respondent (as noted in his amended Rule 4(c) Report) maintains that Petitioner has not met her burden of proof under the Vaccine Act, meaning dismissal is appropriate, but no longer wishes to defend against Petitioner's claim. Opp. at 1–8. Thus, other than reciting the facts of the case and the law applicable to a causation-in-fact claim, Respondent articulates no specific reason to decide this case against the Petitioner.

V. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[8] Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions;

[8] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each *Althen* prong requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." (citing *Moberly*, 592 F.3d at 1322)); *see also Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *appeal docketed,* No. 23-1816 (Fed. Cir. Apr. 28, 2023). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted);

Tarsell v. United States, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum.*

Servs., 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially

where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357,

1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26

("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Standards for Ruling on the Record*

I am resolving Petitioner's claim on the filed record, and the parties have not challenged my determination to do so. Mot. at 1; Opp. at 1. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

The Program has recognized cellulitis as a possible vaccine injury, and petitioners have been granted entitlement in some past cases (though many were settled or conceded without any reasoned causation determination). *See,* e.g., *Elzabad v. Sec'y of Health & Hum. Servs.*, No. 21-1771V, 2023 WL 4418519, at *1 (Fed. Cl. Spec. Mstr. June 15, 2023); *Skinner-Smith v. Sec'y of*

Health & Hum. Servs., No. 14-1212V, 2022 WL 4116896, at *1 (Fed. Cl. Spec. Mstr. Aug. 15, 2022), *reconsideration denied,* No. 14-1212V, 2022 WL 13461862 (Fed. Cl. Sept. 9, 2022); *Salinas v. Sec'y of Health & Hum. Servs.*, No. 17-0609V, 2018 WL 5270106, at *1 (Fed. Cl. Spec. Mstr. Sept. 4, 2018); *Codde v. Sec'y of Health & Hum. Servs.*, No. 16-0812V, 2016 WL 8378159, at *1 (Fed. Cl. Spec. Mstr. Nov. 15, 2016); *Perez v. Sec'y of Health & Hum. Servs.*, No. 15-1023V, 2015 WL 10739340, at *1 (Fed. Cl. Spec. Mstr. Dec. 10, 2015)

In this matter, the *Althen* analysis may be performed succinctly – especially given Respondent's determination to cease his defense, while offering no specific factual objection to the claim. *Althen* prong one has been satisfied because Petitioner has demonstrated, through the opinion of Dr. DeWitt, that vaccines have the potential to cause local infections that could give rise to a cellulitis-like reaction. For *Althen* prong two, there is treater support associating Petitioner's cellulitis with the vaccines she received, which included the covered flu vaccine. Ex. 1 at 331; Ex. 2 at 47; Ex. 5 at 4. Admittedly, the record establishes that Petitioner's contemporaneous physicians did not agree on whether the pneumococcal (a non-covered vaccine) and/or flu vaccine were primarily causal. As both vaccines were administered on the same day and in the same location, there is no way to separate the two in terms of causality. But (applying what is often referred to as a "*Shyface* analysis"), Program claimants need only show a vaccine was a but for, substantial factor in causing an injury, even if another causal factor is present. *Shyface*, 165 F.3d at 1352–53. Here, preponderant evidence supports the conclusion that the flu vaccine was such a substantial factor.

Finally, Petitioner notes that she began experiencing onset within hours of the vaccination, and her symptoms persisted after she sought medical attention for her cellulitis days later—a medically acceptable timeframe given the injury. Saville Aff. I at 2; Saville Aff. II at 1–2. Thus, the third *Althen* prong is satisfied.

Otherwise, there are no other bases for denying entitlement. Respondent has offered no evidence to suggest that Petitioner's cellulitis was caused by any factor unrelated to her vaccination, for example. And I find as well (though the evidence is thin on this particular issue) that six months of severity post-injury have been established. Petitioner's witness statements aver that she still feels pain when pressure is applied to the scars that formed at each injection site, and that this sensation post-dated vaccination for some time. *See* Saville Aff. I at 4; Saville Aff. II at 3. This is enough to establish six months of severity attributable to cellulitis.

Importantly, however (for purpose of calculation of damages in this case), I cannot find on the existing record that Petitioner's claims of fatigue are related or attributable to her vaccine-induced cellulitis. Nothing filed by Petitioner, including Dr. DeWitt's report and associated medical literature, suggests fatigue is a cellulitis sequela, and no other proof supports that finding.

Any award of pain and suffering, or care costs associated with the cellulitis, will necessarily exclude fatigue and costs associated thereto.

CONCLUSION

Petitioner has provided preponderant evidence a causation-in-fact claim. Petitioner is thus entitled to compensation. **The parties are hereby ordered to contact Chambers on or before September 8, 2023, to set a mutually-acceptable date for a status conference to discuss the resolution of damages.**

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master